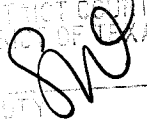


IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

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CLERK US DISTRICT COURT
WESTERN DISTRICT OF TEXAS
BY 

BOARD OF REGENTS,
THE UNIVERSITY OF TEXAS
SYSTEM, AND TISSUEGEN, INC.,
PLAINTIFFS,

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V.

CAUSE NO. 1-17-CV-1084-LY

ETHICON, INC. AND
ETHICON US, LLC
DEFENDANTS.

MEMORANDUM OPINION AND ORDER REGARDING
CLAIMS CONSTRUCTION

Before the court in the above-styled and numbered patent-infringement action are the parties' Joint Claim Construction Statement filed July 25, 2018 (Doc. #29); Plaintiffs Board of Regents, The University of Texas System and TissueGen, Inc.'s (collectively, the "Board") Opening Claim Construction Brief filed September 10, 2018 (Doc. #41); Defendants Ethicon, Inc. and Ethicon US, LLC's (collectively, "Ethicon") Opening *Markman* Brief filed September 17, 2018 (Doc. #48); Ethicon's and the Board's Responsive Claim Construction Briefs filed October 1, 2018 (Docs. #52 & 53). The court commenced a claims-construction hearing on October 11, 2018, that concluded on October 12, 2018. See *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). After considering the patents and their prosecution history, the parties' claim-construction briefs, the applicable law, and arguments of counsel, the court renders its order with regard to claims construction.

I. Introduction

The court construes the claims of United States Patent Nos. 6,596,296 (“the ’296 Patent”) entitled “Drug Releasing Biodegradable Fiber Implant” and 7,033,603 (“the ’603 Patent”) entitled “Drug Releasing Biodegradable Fiber for Delivery of Therapeutics” (collectively “the Asserted Patents”). Plaintiff The Board of Regents, The University of Texas System is the owner of the Asserted Patents, and Plaintiff TissueGen is the exclusive licensee of the Asserted Patents. The Asserted Patents relate to biodegradable polymer fiber compositions containing therapeutic chemical agents that are released over time. The Board alleges that Ethicon infringes claims of the Asserted Patents through making, using, offering for sale, selling or importing infringing products.

II. Legal Principles of Claim Construction

Determining infringement is a two-step process. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384 (1996) (“[There are] two elements of a simple patent case, construing the patent and determining whether infringement occurred”). First, the meaning and scope of the relevant claims must be ascertained. *Id.* Second, the properly construed claims must be compared to the accused device. *Id.* Step one, claim construction, is the current issue before the court.

Claim construction is “‘exclusively’ for ‘the court’ to determine.” *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 835 (2015) (quoting *Markman*, 517 U.S. at 372). The “words of a claim ‘are generally given their ordinary and customary meaning.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp v. Conceptiontronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). “[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at

the time of the invention” *Id.* at 1313. The person of ordinary skill in the art is deemed to have read the claim term in the context of the entire patent. *Id.* Therefore, to ascertain the meaning of a claim, a court must look to the claim, the specification, and the patent’s prosecution history. *Id.* at 1314–17; *Markman*, 52 F.3d at 979.

Claim language guides the court’s construction of a claim term. *Phillips*, 415 F.3d at 1314. “[T]he context in which a term is used in the asserted claim can be highly instructive.” *Id.* Other claims, asserted and unasserted, can provide additional instruction because “terms are normally used consistently throughout the patent” *Id.* Differences among claims, such as additional limitations in dependent claims, can provide further guidance. *Id.* at 1314–15.

Claims must also be read “in view of the specification, of which they are a part.” *Markman*, 52 F.3d at 979. “[T]he specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). In the specification, a patentee may define a term to have a meaning that differs from the meaning that the term would otherwise possess. *Id.* at 1316. In such a case, the patentee’s lexicography governs. *Id.* The specification may also reveal a patentee’s intent to disavow claim scope. *Id.* Such intention is dispositive of claim construction. *Id.* Although the specification may indicate that a certain embodiment is preferred, a particular embodiment appearing in the specification will not be read into the claim when the claim language is broader than the embodiment. *Electro Med. Sys., S.A. v. Cooper Life Scis., Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994).

The prosecution history is another tool to supply the proper context for claim construction because it demonstrates how the inventor understood the invention. *Phillips*, 415 F.3d at 1317. A patentee may also serve as his own lexicographer and define a disputed term in

prosecuting a patent. *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1356 (Fed. Cir. 2004). Similarly, distinguishing the claimed invention over the prior art during prosecution indicates what a claim does not cover. *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1378–79 (Fed. Cir. 1988). The doctrine of prosecution disclaimer precludes a patentee from recapturing a specific meaning that was previously disclaimed during prosecution. *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). A disclaimer of claim scope must be clear and unambiguous. *Middleton, Inc. v. 3M Co.*, 311 F.3d 1384, 1388 (Fed. Cir. 2002).

Although “less significant than the intrinsic record in determining the legally operative meaning of claim language,” the court may rely on extrinsic evidence to “shed useful light on the relevant art.” *Phillips*, 415 F.3d at 1317 (internal quotations omitted). Technical dictionaries and treatises may help the court understand the underlying technology and the manner in which one skilled in the art might use a claim term, but such sources may also provide overly broad definitions or may not be indicative of how a term is used in the patent. *See id.* at 1318. Similarly, expert testimony may aid the court in determining the particular meaning of a term in the pertinent field, but “conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court.” *Id.* Generally, extrinsic evidence is “less reliable than the patent and its prosecution history in determining how to read claim terms” *Id.* Extrinsic evidence may be useful when considered in the context of the intrinsic evidence, *id.* at 1319, but it cannot “alter a claim construction dictated by a proper analysis of the intrinsic evidence,” *On-Line Techs., Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1139 (Fed. Cir. 2004). To the extent the court “make[s] subsidiary factual findings about th[e] extrinsic evidence,” the court construes the claims in light of those factual findings. *Teva*, 135 S. Ct. at 841.

III. Discussion

A. Agreed Constructions

The parties agree to the construction of two claim terms. The court adopts the agreed construction of those terms as listed in the table below.¹

Claim Term/Phrase	Adopted Agreed Construction
“fiber” [’296 Patent, Claims 1, 4, 11, 16, 17, 20, 26; ’603 Patent, Claims 1, 2, 6, 11, 13, 19]	No construction required ²
“hydrogel” [’603 Patent, Claims 1, 6, 19]	a colloid in which a dispersed phase (colloid) is combined with a continuous phase (water) to produce a viscous jellylike product

B. Disputed Terms

The parties dispute the construction of seven terms. Each disputed term is discussed separately.

1. “composed of”

The parties’ proposed constructions of this term, as used in Claims 1, 4, 11, 16, 17, 20 and 26 of the ’296 Patent, are listed in the following table:

¹ Throughout, the **bolded** claim terms indicate the court’s adopted construction.

² This term was initially disputed by the parties, but the Board agrees in its opening brief that the term needs no construction.

the Board's Proposed Construction	Ethicon's Proposed Construction
No construction is necessary because term is used consistent with plain and ordinary meaning	a closed transition phrase meaning "consisting of only the first phase and the second phase"

The parties dispute whether "composed of" is an open or closed transition phrase. A claim using an open transition phrase covers compositions with additional, unlisted elements. *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1244 (Fed. Cir. 2001). In contrast, closed transition phrases limit the claim scope to only the recited elements. *Id.* at 1245. Courts look to the facts of each case to determine whether "composed of" is completely closed or is "open to 'unlisted ingredients that do not materially affect the basic and novel properties of the invention.'" *Id.* (quoting *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998)). The '296 Patent uses "composed of" in the latter fashion.

The specification expressly describes embodiments of the claimed fiber that include components not listed in Claim 1 or any dependent claim. For example, the specification contemplates fibers with multiple concentric polymer layers and "molecules attached to the core fiber to increase the adhesion of the coating polymer." '296 Patent, 20:7–21. Similarly, the specification describes fibers with an additional "polymer segment that acts as a sealant so that the finished fibers can be cut to pre-specified lengths . . . [and] sealed at both ends." *Id.* at 19:66–20:1. Therefore, the patentee would not have intended "composed of" to strictly limit Claim 1 to only a first phase and a second phase. See *Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1277 (Fed. Cir. 2008) ("At leas[t] where claims can reasonably be interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment, absent

probative evidence to the contrary.”). Whether these additional elements, or others not described in the specification, are material to the invention is a question of fact. *AFG*, 239 F.3d at 1247.

Ethicon contends that the prosecution history demands a closed construction. Specifically, Ethicon points to the patentee’s characterization of the invention as a “two-phase system.” However, the court finds no inconsistency in this characterization and a partially open construction that includes additional, immaterial elements. Furthermore, the patentee did not distinguish the invention from prior art based on the exclusivity of the phrase “composed of.” Therefore, the prosecution record does not show that the inventor “limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Phillips*, 415 F.3d at 1317.

Accordingly, the court concludes that “composed of” is **“open to ‘unlisted ingredients that do not materially affect the basic and novel properties of the invention.’”** See *AFG*, 239 F.3d at 1245.

2. “phase”

The parties’ proposed constructions of this term, as used in Claims 1, 4, 11, 16, 17, 20, and 26 of the ’296 Patent, are listed in the following table:

the Board’s Proposed Construction	Ethicon’s Proposed Construction
“a phase in an emulsion / an emulsion”	“a portion of the fiber that is homogenous throughout, has definable boundaries, and can be separated physically from other phases” Alternatively: “a portion of the fiber that is of uniform composition and has defined boundaries”

The Board argues that because “phase” never appears by itself in the claims, the term requires no construction. The Board asserts that defining “phase” alone divorces the term from

the context in which it is used in the claims and specification. If the term is defined, the Board argues that “phase” should be given the same meaning it has when referring to an emulsion.

Ethicon asserts the Board described the invention as being “made up of two phases” to distinguish prior art during prosecution. Therefore, Ethicon argues the term should be given its ordinary technical meaning. Ethicon cites several scientific dictionaries and an expert declaration in support of its construction.

The court concludes the term “phase”—standing alone—requires no construction. Each time it is used in the '296 Patent, “phase” appears in conjunction with “first” or “second.” Because the court construes “first phase” and “second phase,” defining “phase” alone would be redundant and confusing. Furthermore, Ethicon raises no dispute over claim scope that is resolved by construing “phase,” but left unresolved by construing “first phase” and “second phase.” See *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) (“Claim construction is a matter of resolution of disputed meanings and technical scope, not an obligatory exercise in redundancy.”). Therefore, the court concludes that **no construction of the term is necessary.**

3. “first phase”

The parties’ proposed constructions of this term, as used in Claims 1, 4, 11, 16, 17, 20, and 26 of the '296 Patent, are listed in the following table:

the Board’s Proposed Construction	Ethicon’s Proposed Construction
“continuous phase comprising the polymer that makes up the fiber” Alternatively: “the first substance is made up of polymer”	“the polymer that makes up the fiber” Alternatively: “the polymer of the fiber”

As reflected by their proposed constructions, the parties agree that “first phase” refers to the polymer portion of the fiber. The Board argues the “continuous phase” limitation of its construction reflects the corresponding phase of the emulsion used in fabricating the fibers. Ethicon responds that the Board’s construction improperly reclaims fibers containing an emulsion—a position abandoned during prosecution. The court agrees with Ethicon.

The “first phase” of Claim 1 is derived from the polymer phase of the emulsion used during fiber fabrication. *See* '296 Patent, 17:40–19:36 (describing fiber fabrication process). In the final step of fabrication, the fibers are dried. *Id.* at 18:36–40. Consequently, the fiber no longer contains any fluid, let alone an emulsion.³ Therefore, defining “first phase” as the “continuous phase”—a term of art used to describe an emulsion—improperly suggests the fibers include an emulsion. Without the “continuous phase” limitation, both parties’ constructions define “first phase” as the polymer portion of the fiber. Therefore, the court concludes the construction of “first phase” to be **the polymer portion of the fiber**.

4. “second phase”

The parties’ proposed constructions of this term, as used in Claims 1, 4, 11, 16, 17, 20, and 26 of the '296 Patent, are listed in the following table:

the Board’s Proposed Construction	Ethicon’s Proposed Construction
<p>“dispersed phase containing one or more therapeutic agents”</p> <p>Alternatively: “the second substance [which] contains drug(s) and particles of droplets of the second substance are dispersed within the first substance”</p>	<p>“the inner phase of the fiber containing one or more therapeutic agents”</p> <p>Alternatively: “the inner drug region or regions of the fiber, which are separate from the first phase and contain no polymer”</p>

³ For this reason, an earlier version of Claim 1 reciting “fibers compris[ing] an emulsion” was rejected for lack of written description under 35 U.S.C. § 112.

As reflected by their proposed constructions, the parties agree that “second phase” refers to the portion of the fiber containing therapeutic agents or drugs. The parties primarily dispute whether the “second phase” must be dispersed throughout the first phase or is simply an inner region. The Board argues the “dispersed” limitation accurately reflects the result of fabricating fibers from an emulsion. The Board urges that Ethicon’s construction covers fibers with a drug-containing inner core surrounded by polymer—a configuration described in prior art that the patentee distinguished during prosecution. Ethicon responds that the “dispersed” language improperly reads an emulsion back into the claim and asserts that its definition aligns with the patentee’s characterization of the second phase during prosecution. The court agrees with the Board.

The specification and prosecution history show that the second phase must be dispersed throughout the first phase. During fabrication, the polymer phase “precipitate[s] upon itself, forming the outer sheath of a fiber and trapping virtually all of the [drug-containing] dispersed aqueous phase of the emulsion within the forming fiber.” ’296 Patent, 18:1–28. Figures 4, 6 and 7 similarly show that the second phase is made up of discrete, drug-containing regions dispersed throughout the first phase. *Id.* figs. 4, 6, 7. And during prosecution, the patentees distinguished the invention over prior art on the basis of the therapeutic agents being “within an immiscible discontinuous phase or internal porous structure of the fiber.”

However, because the claimed fiber is dried in the final stage of production, it no longer contains an emulsion. Therefore, referring to the second phase as the “dispersed phase”—a term of art used to describe an emulsion—is improper.

Accordingly, the court concludes the construction of “second phase” to be **the discrete drug-containing regions dispersed throughout the fiber.**

5. “immiscible”

The parties’ proposed constructions of this term, as used in Claims 1, 4, 11, 16, 17, 20, and 26 of the ’296 Patent, are listed in the following table:

the Board’s Proposed Construction	Ethicon’s Proposed Construction
Plain and ordinary meaning: “not miscible” Alternatively: “incapable of mutual solution at the proportions used”	“incapable of being mixed” Alternatively: “cannot be mixed or blended together”

The parties dispute whether the term “immiscible” requires construction. The Board argues the claims use the term in accordance with its plain and ordinary meaning: “not miscible.” Ethicon responds that “miscibility” describes a tendency of two substances to mix, ranging from immiscible to totally miscible. Ethicon alleges that a fundamental dispute over where “immiscible,” as used in the ’296 Patent, falls in that range necessitates construction. Ethicon argues the prosecution history, technical dictionaries, and expert declarations support construing “immiscible” to mean “incapable of being mixed.” The Board responds that basic chemistry principles teach that no set of substances are “incapable of being mixed” in any proportion, making Ethicon’s construction scientifically inaccurate. Therefore, the Board proposes an alternate construction: “incapable of mutual solution at the proportions used.”

The court finds that “immiscible” requires construction. “Immiscible” is a technical term with unclear scope, and Ethicon raises a genuine dispute over the term’s scope. *See U.S. Surgical*, 103 F.3d at 1568 (“Claim construction is a matter of resolution of disputed meanings and technical scope”); *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) (“When the parties present a fundamental dispute regarding the scope of a claim term, it is the court’s duty to resolve it.”).

Before addressing the miscibility-scale issue, the court concludes that “immiscible,” as used in the ’296 Patent, refers to two substances’ tendency to dissolve in one another, rather than their tendency to mix.⁴ The stable emulsion used in fiber fabrication may accurately be described as a mixture of the aqueous and organic phases, but is not a solution of the two phases. *See* ’296 Patent, 18:1–11. Dr. William G. Pitt, the Board’s expert, provided an instructive example: “When mechanically forced to mix (such as shaking oil and vinegar salad dressing), one phase can become dispersed in the other, but over time they will separate” Describing “immiscible” as a tendency to mix, rather than dissolve, confusingly and improperly suggests that the second phase may not be dispersed throughout the first phase. Therefore, to the extent extrinsic evidence in the record describes miscibility as a tendency to mix, the court will instead use “dissolve” to accurately reflect the way the term is used in the ’296 Patent.

Turning to the miscibility-scale issue, several unasserted claims of the ’296 patent, as well as the portions of the specification supporting those claims, suggest immiscibility does not depend on the proportions used. Dependent claims 6–9, 24, and 32 describe a variation of the fiber of Claim 1 in which the concentration of therapeutic agents varies along the length of the fiber. ’296 Patent, 28:4–18, 29:6–8, 30:13–16. The specification describes the process for creating such fibers, and Figure 6 visually depicts this fiber variation. *Id.* at 19:40–55, fig. 6. Although the ratio of therapeutic agent to polymer varies in such a fiber, the first and second phases must still be “immiscible,” suggesting that immiscibility does not depend on the proportions used.

The rest of the specification provides little instruction for construing “immiscible.” As Ethicon points out, the specification never uses the term “immiscible.” Rather, when describing

⁴ At the claims-construction hearing, both parties agreed to such a construction.

the first phase, the specification requires "low miscibility with water." Although "low miscibility" suggests the first (polymer) phase and second (aqueous) phase have some capability of dissolving, Claim 1 simply does not use the phrase "low miscibility." Thus, the specification's use of different terms provides little guidance in construing "immiscible."

The prosecution history does not provide much help either. Ethicon notes the patentee described the second phase as "separate" from the first phase to distinguish prior art during prosecution. However, immediately before that characterization, the patentee stated that the prior art "does not teach or suggest the separation of immiscible phases in the formed fibers." This earlier statement suggests that "separate" and "immiscible" had different meanings to the patentee. Therefore, the prosecution history, although appearing to support Ethicon's position, ultimately holds little weight in the court's final construction.

With minimal guidance from the intrinsic evidence, the court turns to the extrinsic evidence, which weighs heavily in favor of "immiscible" meaning incapable of dissolving. Ethicon offers definitions of "immiscible" from four chemistry dictionaries published before the time of invention, all but one of which define "immiscible" as incapable of mixing. *See, e.g.,* MCGRAW-HILL DICTIONARY OF CHEMICAL TERMS 216 (1984) ("Pertaining to liquids that will not mix with each other."); *but see* DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 652 (26th ed. 1981) ("Not *susceptible* to being mixed." (emphasis added)). Furthermore, both the Board's expert, Pitt, and Ethicon's expert, Dr. David J. Mooney, suggest that "immiscible" refers to two chemicals that are incapable of dissolving. Pitt's definition implies incapability: "[I]f molecules of one chemical and molecules of another chemical *cannot* mix into each other and remain *adjacent* to each other without creating high energy, then the chemicals are said to be

immiscible.” (emphasis added). Perhaps not surprisingly, Mooney makes incapability explicit: “‘immiscible’ substances . . . have no capacity to mix in any proportion.”

The Board responds that because Ethicon and Mooney fail to identify any set of chemicals which are incapable of dissolving at any proportion, Ethicon’s construction is scientifically incorrect. But Ethicon has no burden to identify such substances. And neither party’s expert provides a scientific basis for concluding that all chemicals will dissolve at some proportion. Therefore, the court finds no support in the record for concluding that Ethicon’s construction is scientifically incorrect.

Although no individual source of evidence provides compelling support for either party’s construction, the totality of evidence weighs in favor of construing “immiscible” to mean incapable of dissolving regardless of the proportions used. Therefore, court concludes the construction of “immiscible” to be **incapable of dissolving into one another**.

6. “gel”

The parties’ proposed constructions of this term, as used in Claims 1, 2, 6, 11, 13, and 19 of the ’603 Patent, are listed in the following table:

the Board’s Proposed Construction	Ethicon’s Proposed Construction
“a colloidal system with at least two phases, one of which forms a continuous three-dimensional network that acts as an elastic solid”	“a colloidal system with at least two phases, one of which forms a continuous three-dimensional network that acts as an elastic solid, i.e., a liquid system that acts like a solid”

The parties dispute whether “gel” requires a liquid component. The Board argues that because the ’603 Patent explicitly defines “gel,” the patentee’s definition governs and the inquiry stops there. Ethicon argues that the ’603 Patent specification and extrinsic evidence support the “i.e. clause” of its proposed construction. The court agrees with the Board.

The '603 Patent explicitly defines "gel": "As used herein, the term "gel" refers to a colloidal system with at least two phases, one of which forms a continuous three-dimensional network that acts as an elastic solid." '603 Patent, 5:36–39. Where "the specification . . . reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess . . . the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. In such situations, "there is no need to search further for the meaning of the term." *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998).

The court concludes the construction of "gel" to be **a colloidal system with at least two phases, one of which forms a continuous three-dimensional network that acts as an elastic solid.**

7. "an emulsion consisting essentially of a gel or hydrogel"

The parties' proposed constructions of this term, as used in Claim 19 of the '603 Patent, are listed in the following table:

the Board's Proposed Construction	Ethicon's Proposed Construction
"an emulsion consisting of essentially a dispersed gel or hydrogel phase"	"an emulsion having only the following material elements: a gel or hydrogel"

The parties dispute whether Claim 19 requires an emulsion. The Board asserts that several examples from the specification support its addition of "dispersed" and "phase" to the term and argues that Ethicon's construction effectively reads "emulsion" out of the claim. Ethicon responds that the specification provides several examples of a fiber that includes a gel or hydrogel, but not in a dispersed phase. Ethicon further argues that because "gel" and "hydrogel" have already been construed, the language added by the Board is unnecessary. The court agrees with Ethicon.

The specification contemplates embodiments of the claimed drug-delivery fiber that include a gel or hydrogel, but not in a dispersed phase. *E.g.*, '603 Patent, 6:17–20 (“In certain embodiments, one or more of the layers of the circumscribed fibers comprise a hydrogel or gel in the wall . . . or in the bore of the fiber.”). These embodiments are distinct from those incorporating a gel or hydrogel as a dispersed phase. *See id.* at 6:20–22 (“In additional embodiments, a gel or hydrogel is incorporated as a dispersed phase . . .”). Thus, the gel or hydrogel of Claim 19 cannot be limited to a dispersed phase.

The Federal Circuit has identified “consisting essentially of” as a transition phrase that typically means “the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.” *PPG*, 156 F.3d at 1354. Although the default definition does not apply when a patentee explicitly ascribes another meaning to “consisting essentially of,” that exception does not apply here. *Id.* at 1355. Accordingly, the court concludes the construction of “an emulsion consisting essentially of a gel or hydrogel” to be **an emulsion having only the following material elements: a gel or hydrogel.**

C. *Summary Table of Agreed and Disputed Terms*

Term	Court's Construction
“fiber” ['296 Patent, Claims 1, 4, 11, 16, 17, 20, 26; '603 Patent, Claims 1, 2, 6, 11, 13, 19]	No construction necessary
“hydrogel” ['603 Patent, Claims 1, 6, 19]	a colloid in which a dispersed phase (colloid) is combined with a continuous phase (water) to produce a viscous jellylike product

<p>“composed of”</p> <p>[’296 Patent, Claims 1, 4, 11, 16, 17, 20, 26]</p>	<p>open to unlisted ingredients that do not materially affect the basic and novel properties of the invention</p>
<p>“phase”</p> <p>[’296 Patent, Claims 1, 4, 11, 16, 17, 20, 26]</p>	<p>No construction necessary</p>
<p>“first phase”</p> <p>[’296 Patent, Claims 1, 4, 11, 16, 17, 20, 26]</p>	<p>the polymer portion of the fiber</p>
<p>“second phase”</p> <p>[’296 Patent, Claims 1, 4, 11, 16, 17, 20, 26]</p>	<p>the discrete drug-containing regions dispersed throughout the fiber</p>
<p>“immiscible”</p> <p>[’296 Patent, Claims 1, 4, 11, 16, 17, 20, 26]</p>	<p>incapable of dissolving into one another</p>
<p>“gel”</p> <p>[’603 Patent, Claims 1, 2, 6, 11, 13, 19]</p>	<p>a colloidal system with at least two phases, one of which forms a continuous three-dimensional network that acts as an elastic solid</p>
<p>“an emulsion consisting of essentially a gel or hydrogel”</p> <p>[’603 Patent, Claim 19]</p>	<p>an emulsion having only the following material elements: a gel or hydrogel</p>

IV. Conclusion

For the above reasons, the court construes the disputed claims as noted and so **ORDERS**.
No other claim terms require construction.

IT IS FURTHER ORDERED that this case is set for a **Scheduling Conference** on February 15, 2019, at 10:30a.m., in Courtroom 7, Seventh Floor, United States Courthouse, 501 W. 5th Street, Austin, Texas 78701. The parties shall meet and confer in advance of that date in an attempt to settle this case. If the case is not settled, the parties shall confer in an attempt to reach agreement on a schedule to follow for the remainder of this case. The court will render a Scheduling Order as a result of the February 15 conference.

SIGNED this 30th day of November, 2018.



LEE YEAKEL
UNITED STATES DISTRICT JUDGE